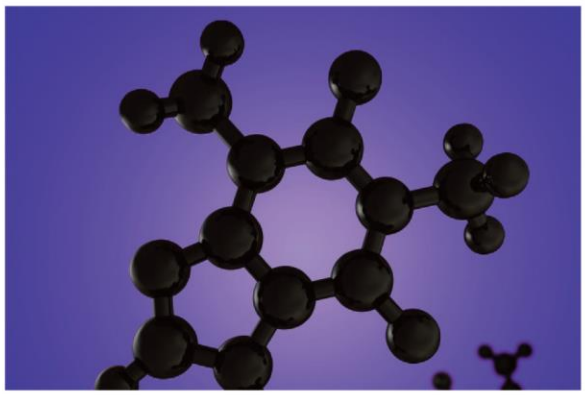
Canadian Food Inspection Agency
Agence canadienne d'inspection des aliments

Targeted Surveys

REPORT

2013-2014

Allergens



Soy in Prepackaged Grain-based Foods

RDIMS 5513964

Canada

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Executive Summary

Targeted surveys are used by the Canadian Food Inspection Agency (CFIA) to both support the prioritization of the Agency's activities to areas of greater concern and provide scientific evidence to address areas of lesser concern. Originally started under the Food Safety Action Plan (FSAP), targeted surveys have been incorporated into the CFIA's regular surveillance activities as a valuable tool for generating essential information on certain hazards in foods, identifying/characterizing new and emerging hazards, informing trend analysis, prompting/refining human health risk assessments, assessing compliance with Canadian regulations, highlighting potential contamination issues, and promoting compliance.

The main objectives of this targeted survey were to obtain baseline information regarding the presence and levels of undeclared soy in single and multiple ingredient prepackaged grain-based foods, and to identify potential food safety concerns related to undeclared soy for the soy-allergic population.

In Canada and in other countries, as part of normal and long-standing agricultural practices, cereal grains are often grown in close proximity to other types of grains, oilseeds, and pulses. In addition, these other grains, oilseeds, and pulses can be harvested, stored, and transported using the same equipment and facilities as those used for cereal grains. Therefore, it is extremely difficult to keep low levels of different crops from getting mixed in with each other, and may lead to the adventitious, or inadvertent, presence of a food allergen, like soy, in other finished grain products (such as wheat-based foods). Soy may also be present in prepackaged food products as a result of cross-contamination prior to or during manufacturing, which may indicate a breakdown in good manufacturing practices or allergen controls.

The presence of an undeclared allergen (like soy) in a food may represent a serious or life-threatening health risk for allergic or sensitive individuals. Health risk assessments have determined that the low levels of soy due to adventitious presence would not be expected to cause a serious, adverse allergic reaction in those with a soy allergy. The Canadian Food Inspection Agency and Health Canada have advised manufacturers and importers that precautionary labelling for soy is not recommended on finished grain-based foods when a low level of soy is detected due to adventitious presence.

A total of 388 samples were collected and analysed for the presence of soy. Samples included a variety of prepackaged grain-based foods that did not declare soy either as an ingredient or in a precautionary statement. Products were either single ingredient (e.g., oat flour) or multiple ingredient finished foods (such as cookies). Of the 388 samples, 171 (44%) were positive for soy and nearly all of these positives were at a very low

concentration. Comparing product types in the survey, wheat flours and baking mixes (many with wheat flour as a main ingredient) had the highest percentage of samples positive for undeclared soy, 54% and 71% respectively.

Since not all detectable levels of soy pose a risk to consumers, positive results were first considered by the CFIA for their potential risk. Appropriate follow-up actions were initiated that reflected the magnitude of the human health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspection, additional directed sampling, a food safety investigation (which may involve a health risk assessment conducted by Health Canada), and recall of products.

The CFIA will continue its surveillance activities and inform the Canadian public and stakeholders of its findings.

1 Introduction

1.1 Targeted Surveys

The Canadian Food Inspection Agency (CFIA) monitors both domestic and imported foods for the presence of allergenic, microbiological, chemical, and physical hazards. One of the tools used to maintain this oversight are targeted surveys, which are a means to establish baseline information on specific hazards and to investigate emerging risks. Targeted surveys are part of the Agency's core activities along with other surveillance strategies, which include the National Chemical Residue Monitoring Program (NCRMP), the National Microbiological Monitoring Program (NMMP), and the Children's Food Project (CFP). The surveys are complementary to other CFIA surveillance activities in that they examine hazards and/or foods that are not routinely included in those monitoring programs.

Targeted surveys are used to gather information regarding the possible occurrence or prevalence of hazards in defined food commodities. These surveys generate essential information on certain hazards in foods, identify or characterize new and emerging hazards, inform trend analysis, prompt or refine human health risk assessments, assess compliance with Canadian regulations, highlight potential contamination issues, and/or influence the development of risk management strategies as appropriate.

Due to the vast number of hazard and food commodity combinations, it is not possible, nor should it be necessary, to use targeted surveys to identify and quantify all hazards in foods. To identify food-hazard combinations of greatest potential health risk, the CFIA uses a combination of scientific literature, the media, and/or a risk-based model developed by the Food Safety Science Committee, a group of federal, provincial and territorial subject matter experts in the area of food safety.

Some hazards are actually a food itself - an undeclared food allergen, which is not a hazard to the majority of the population, can be hazardous to allergic individuals. This targeted survey provided baseline information on the presence of undeclared soy in prepackaged, grain-based products. The survey focussed on single ingredient products (e.g. wheat flour) as well as multiple ingredient products which contained grains as the primary ingredient (such as baked goods). The sampled foods did not have soy in the list of ingredients or in a precautionary statement.

1.2 Acts, Regulations, and Codes of Practice

The specific acts and regulations applicable to this survey are described below.

The *Food and Drugs Act* is the legal authority that governs the sale of food in Canada. The *Canadian Food Inspection Agency Act* stipulates that the CFIA is responsible for enforcing restrictions on the production, sale, composition and content of foods and food products as outlined in the *Food and Drugs Act* and *Food and Drug Regulations* (FDA and FDR).

If a prepackaged food product displays a list of ingredients but does not disclose potential allergens, it may pose a health risk to an allergic consumer. Failure to declare allergenic components may be contrary to subsection 5. (1) of the FDA[1], and such food products may therefore be subject to regulatory measures taken by the CFIA.

Health Canada has made amendments to the FDR to enhance the labelling of priority allergens, gluten sources, and sulphites on prepackaged foods sold in Canada. Some of these amendments require that food allergen and gluten sources be declared on the labels of prepackaged foods having a list of ingredients whenever the protein, modified protein, or protein fractions of the food allergen or gluten source are added to the food product. Due to the complexity of the labelling changes required, and given the extended shelf-life of some processed foods, Health Canada provided manufacturers with 18 months from the date of registration of the regulatory amendments to implement any necessary label changes. Thus, manufacturers were required to comply with Canada's amended food allergen labelling regulations when they came into force on August 4, 2012[2]. The food products analyzed in this survey were sampled after these amended labelling regulations came into force and therefore were required to comply with these new regulations.

The Canadian Grain Regulations permit small percentages of other grains to be present in a harvested cereal crop, recognizing the sometimes unavoidable co-mingling of grains (e.g., barley or wheat in harvested oats)[3]. This low level co-mingling of grains at harvest may lead to the adventitious, or inadvertent, presence of an allergen (e.g., soy) in finished foods. Health risk assessments have determined that the low levels of soy found in prepackaged grain-based foods due to adventitious presence would not be expected to cause a serious, adverse allergic reaction in those with a soy allergy. The CFIA and Health Canada have posted information on the adventitious presence of soy in grain products for both manufacturers/importers of grain-based products[4] and consumers[5], and have not recommended precautionary labelling[6] for soy on finished grain-based foods when a low level of soy is detected due to adventitious presence.

2 Survey Details

2.1 Undeclared Soy in Prepackaged Grain-based Foods

In Canada and in other countries, as part of normal and long-standing agricultural practices, cereal grains are often grown in close proximity to other types of grains, oilseeds, and pulses. In addition, these other grains, oilseeds, and pulses can be harvested, stored, and transported using the same equipment and facilities as those used for cereal grains. Therefore, it is extremely difficult to keep low levels of different crops from getting mixed in with each other, and may lead to the adventitious, or inadvertent, presence of a food allergen, like soy, in other finished grain products (such as wheat-based foods).

The presence of an undeclared allergen in a food is not a health concern for the majority of Canadians. However, undeclared allergens may represent a serious or life-threatening health risk for allergic or sensitive individuals. In Canada, a specific list of food allergens have been identified by Health Canada as being responsible for causing the majority of severe allergic reactions, and these are sometimes referred to as the priority allergens: eggs, milk, mustard, peanuts, seafood (fish, crustaceans, shellfish), sesame, soy, sulphites, tree nuts (almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, and walnuts), and wheat. Soy allergy is most common in infants and typically develops around 3 months of age[7]. There is little information on prevalence rates for soy allergy; a rate[i] of 0.3 - 0.4% in the general population has been noted, with slightly higher rates in children with eczema[8]. Soy allergy is often outgrown by 3 years of age[9,10].

Currently, there is no cure for a food allergy. The most important strategy for a person with a food allergy, or a person choosing food for such an individual, is avoidance of the allergen that can trigger an adverse reaction. Allergens must be appropriately labelled on finished food products to ensure consumers have complete, accurate information when choosing food.

2.2 Rationale

Adventitious presence is not unique to soy, but can occur with other cereal grains and is reflected in the current grain grading standards for quality[3]. This type of presence cannot be completely controlled by good manufacturing practices. Soy may also be present in prepackaged food products if soy was present in an incoming ingredient but not properly labelled on that ingredient, or from cross-contamination prior to or during manufacturing (e.g., other cereal grain products and soy-based products processed with shared

[i]Based on self-reported allergies

equipment). This type of presence may be an indicator of a breakdown in good manufacturing practices or allergen controls.

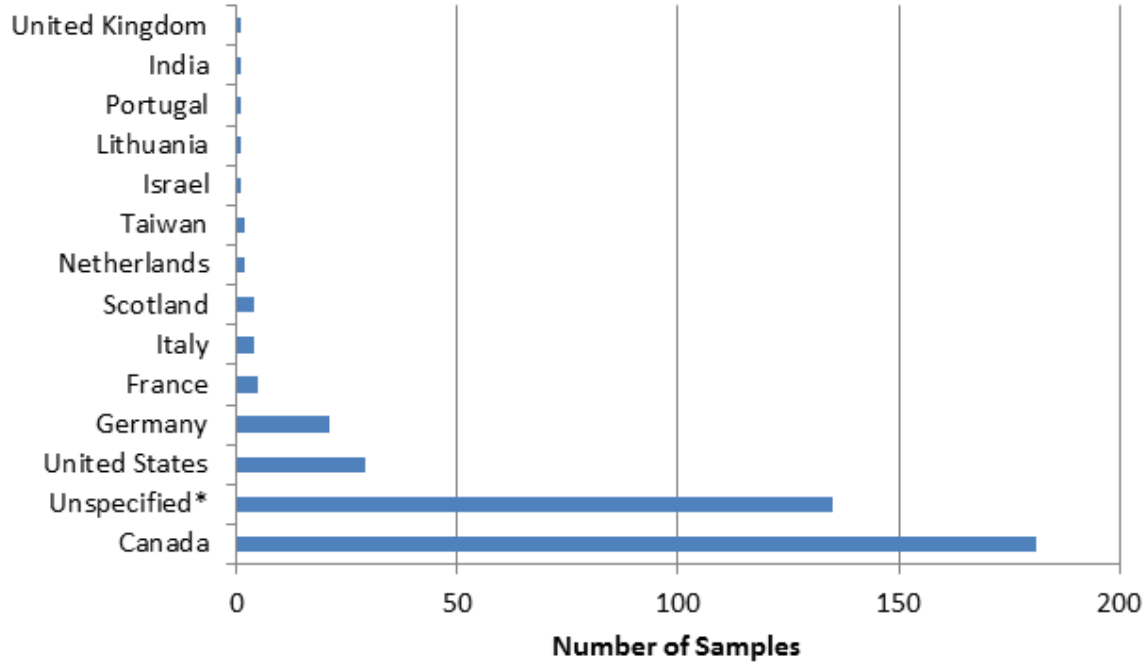
This survey tested foods that were grain-based and did not have soy in the list of ingredients or in a precautionary statement. The main objectives of this survey were to obtain baseline information regarding the presence and levels of undeclared soy in single and multiple ingredient prepackaged grain-based foods, and to identify potential food safety concerns for the soy-allergic population related to the presence of undeclared soy.

2.3 Sample Selection

A total of 388 food samples were collected nationally from retail stores in six Canadian cities between June 2013 and March 2014. Specific brands were not targeted.

This survey targeted prepackaged grain-based foods that did not declare soy either as an ingredient or in a precautionary statement. Single ingredient grain-based foods contained barley, oats, wheat, or rye. Multiple ingredient finished foods included baked goods (e.g., cakes, pastries, crêpes), baking mixes (e.g., cake, cookie, muffin, scone), bread (e.g., loaves, naan, buns, pita, tortillas), cookies, and crackers/croutons.

The 388 survey samples included 181 domestic products, 72 imported products, and 135 products of unspecified origin. An unspecified country of origin refers to those samples for which the origin is not indicated on the product label. It is important to note that the products sampled often contained the statement “packaged in Country X”, “imported for Company A in Country Y” or “manufactured for Company B in Country Z”, and though the labelling meets the intent of the regulatory standard, it does not specify the true origin of the product ingredients. Only those products labelled with a clear statement of “Product of”, “Prepared in”, “Made in”, “Processed in”, and “Manufactured by” were considered as being from a specific country of origin. The distribution of samples collected in this survey with respect to the country of origin (as indicated on the product label) is depicted in Figure 1.



*Unspecified refers to those samples for which the country of origin could not be determined from the product label

Figure 1. Distribution of prepackaged grain-based food samples by country of origin (arranged by increasing number of samples)

2.4 Limitations

This targeted survey was designed to provide a snapshot of the presence and levels of undeclared soy in selected foods available to Canadian consumers, and highlight commodities that warrant further investigation. The limited number of samples analyzed represents a small fraction of the products available to consumers. Therefore, care must be taken when interpreting and extrapolating these results.

As previously mentioned, Canadian regulations permit small percentages of other grains to be present in domestically-harvested cereal crops, and subsequently those other grains may be inadvertently present in finished foods made from those crops. International regulations and practices may permit different maximum levels of grain co-mingling in their harvested cereal crops (and exported products) than those in Canada. Few samples found positive for soy in this survey could be verified to contain only Canadian grain. Thus, few inferences or conclusions were made regarding the data with respect to country of origin or the source of undeclared soy/cross-contamination (refer to Section 2.3).

Analysis was completed on products as available on the Canadian retail market. Samples were tested as sold, meaning that the product was not prepared as per the package

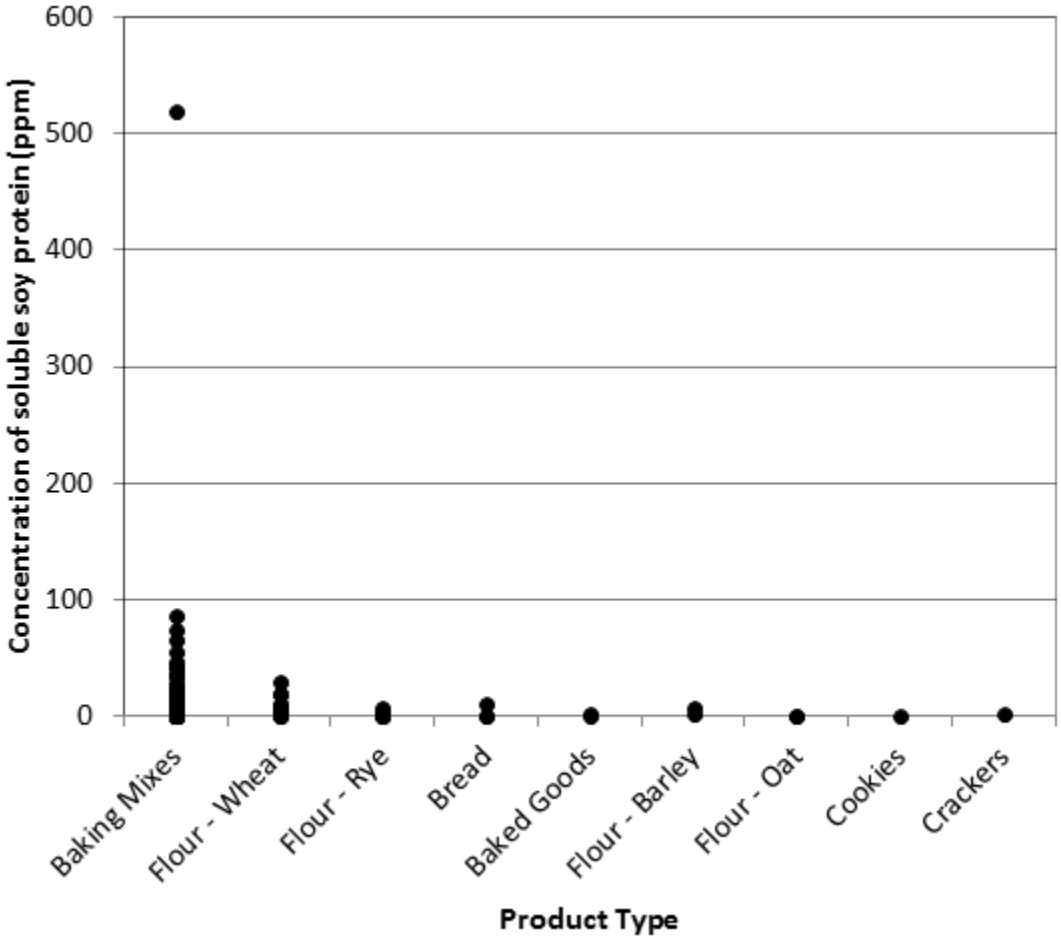
instructions, if applicable. Some of the products sampled in this survey are considered ingredients and/or require preparation prior to consumption (i.e., mixing with liquid).

3 Results and Discussion

3.1 Overview of Survey Results

Samples in the Soy in Prepackaged Grain-based Foods Targeted Survey were analyzed by an ISO 17025 accredited food testing laboratory under contract with the Government of Canada. Commercially available ELISA-based allergen testing kits were used for analysis. These kits are manufactured by various companies who may use different materials to calibrate and standardize their tests. Consequently, when data is generated by these different kits, the results cannot necessarily be directly compared to one another. To eliminate this issue, CFIA usually converts the result found to a common unit of measurement (i.e., concentration of soluble allergen protein in parts per million (ppm)) by applying a conversion factor. The details relevant to interpretation of the results of this survey can be found in sections below.

A total of 171 of the 388 samples (42 domestic, 23 imported, and 106 of unspecified origin) analysed had a detectable level of soy (44%), and most of those samples found positive for undeclared soy were baking mixes. Figure 2 below shows the range of concentrations found in samples positive for undeclared soy. Refer to the Appendix for a summary of samples found positive for undeclared soy by product type.



Note: Only values above the limit of detection are displayed in the graph

Figure 2. Concentration of soluble soy protein detected in finished foods by product type (arranged by decreasing number of positive samples)

When comparing the different product types in this survey, baking mixes and wheat flours had the highest percentages of samples positive for undeclared soy (71% and 54%, respectively). The single baking mix product that had a relatively elevated level of soy must be prepared prior to consumption. Taking into account the directions for preparation on the mix, the concentration of soy in the product as it would be consumed would be lower and closer to the levels of soy noted in some of the ready-to-eat foods sampled in this survey. Breads and baked goods had the lowest percentages of samples positive for undeclared soy (each 5%). All samples positive for undeclared soy had low concentrations. The levels of soy detected in samples in this survey generally support that soy was either adventitiously present or cross-contamination may have occurred prior to or during manufacturing. The levels detected in this survey do not suggest that soy was intentionally added.

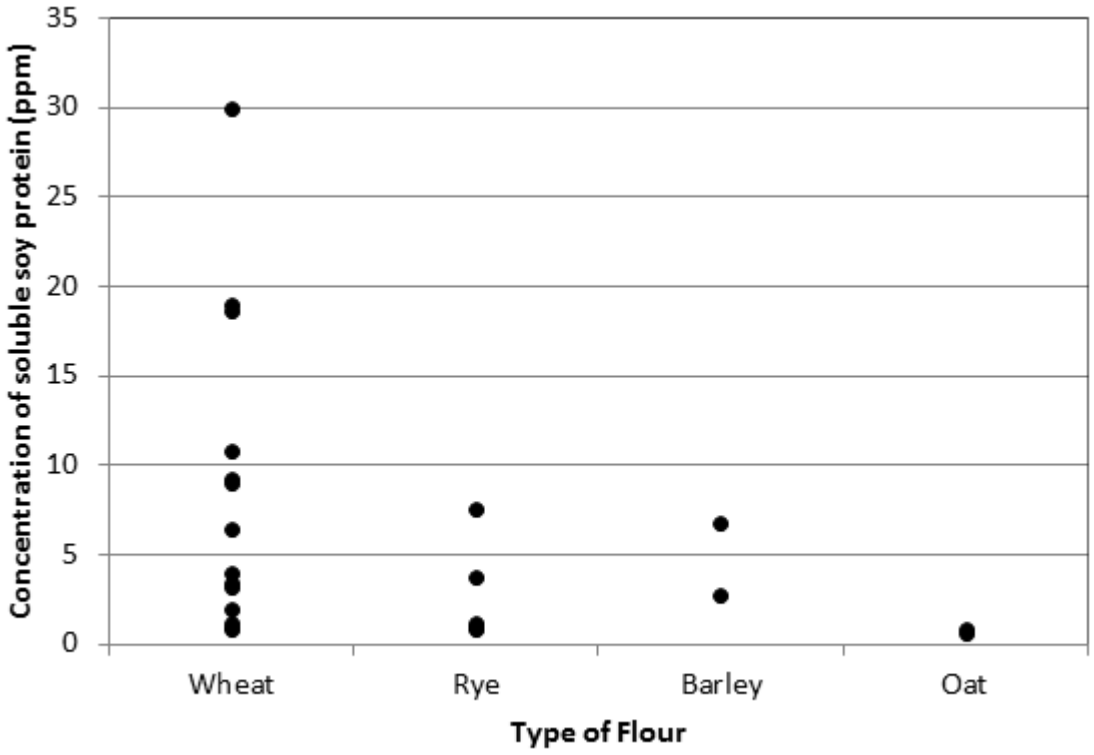
Since not all detectable levels of soy pose a risk to consumers, positive results were first considered by the CFIA for their potential risk. Appropriate follow-up actions were initiated that reflected the magnitude of the human health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspection, additional directed sampling, a food safety investigation (which may involve a health risk assessment conducted by Health Canada), and recall of products.

The following sections present the analysis results for undeclared soy in each product type.

3.2 Results by Product Category and Product Type

3.2.1 Single Ingredient Finished Foods

Four types of single ingredient grain-based finished foods were sampled in this survey. The 66 samples analyzed included barley flours, oat flours, rye flours, and wheat flours (all-purpose white, whole wheat, self-rising, and cake flours). Of these four types of flour, wheat flours had the highest percentage of samples positive for undeclared soy, 54%. Figure 3 shows the range of concentrations found in single ingredient samples positive for undeclared soy by product type.



Note: Only values above the limit of detection are displayed in the graph

Figure 3. Concentration of soluble soy protein detected in single ingredient finished foods by product type (arranged by decreasing number of positive samples)

The very low levels of soy detected in flour samples and the fact that these are minimally processed finished foods generally support that soy was adventitiously present. Relative to other types of flour sampled in this survey, the higher percentage of wheat flour samples found positive for low levels of undeclared soy may indicate that finished foods made from this particular grain may be more prone to the adventitious presence of soy. The levels detected in flour samples do not indicate that soy was intentionally added.

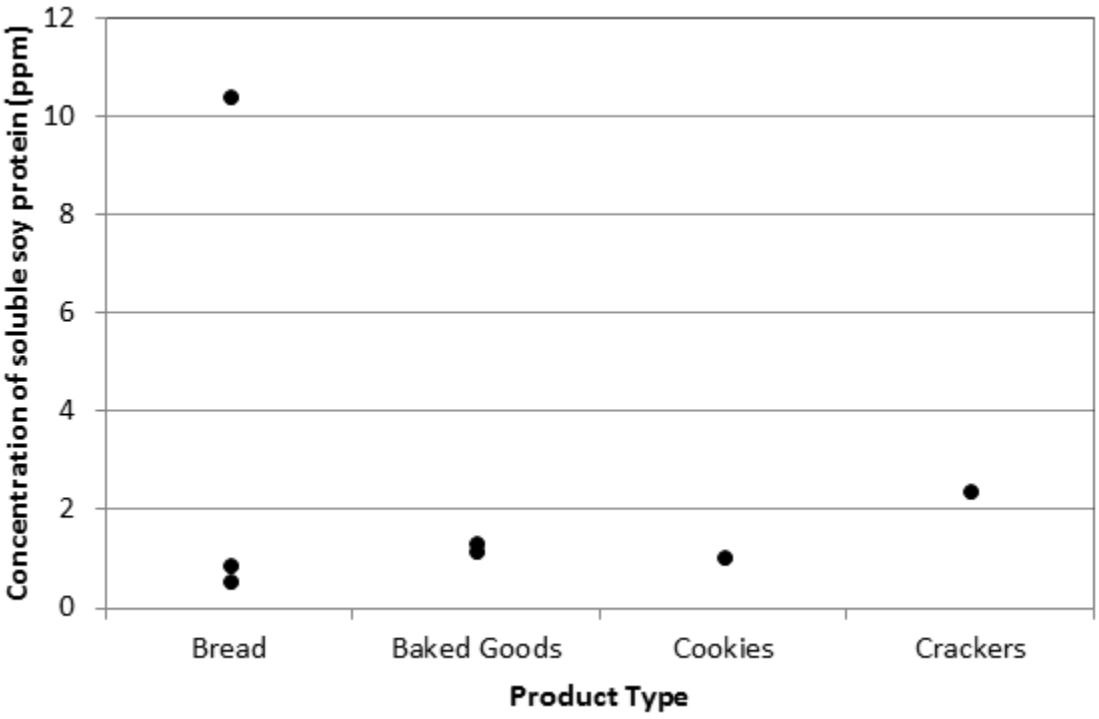
3.2.2 Multiple Ingredient Finished Foods

Five types of multiple ingredient grain-based finished foods were sampled in this survey: baked goods, baking mixes, breads, cookies, and crackers/crispbreads/croutons.

The 42 samples of baked goods analyzed included cakes, crêpes, pancakes, pastries, and waffles, all of which were ready-to-eat/heat-and-serve. 196 samples of dry baking mixes (i.e., not prepared) were tested and included cake, cookie, dessert square, muffin, pancake/waffle, pie, pizza dough, quickbread, and scone mixes. 65 bread samples (all ready-to-eat/heat-and-serve) included bagels, biscuits/buns, loaf breads (various single

grain and multi-grain types), naan, pita, pizza crusts, quickbreads, and tortillas. Cookies and crackers/crispbreads/croutons were also analyzed (11 and 8 samples respectively).

Of these five types of finished foods, baking mixes had the highest percentage of samples positive for undeclared soy (71%). Figures 4 (baked goods, breads, cookies, and crackers/crispbreads/croutons) and 5 (baking mixes only) show the range of concentrations found in multiple ingredient samples positive for undeclared soy by product type.

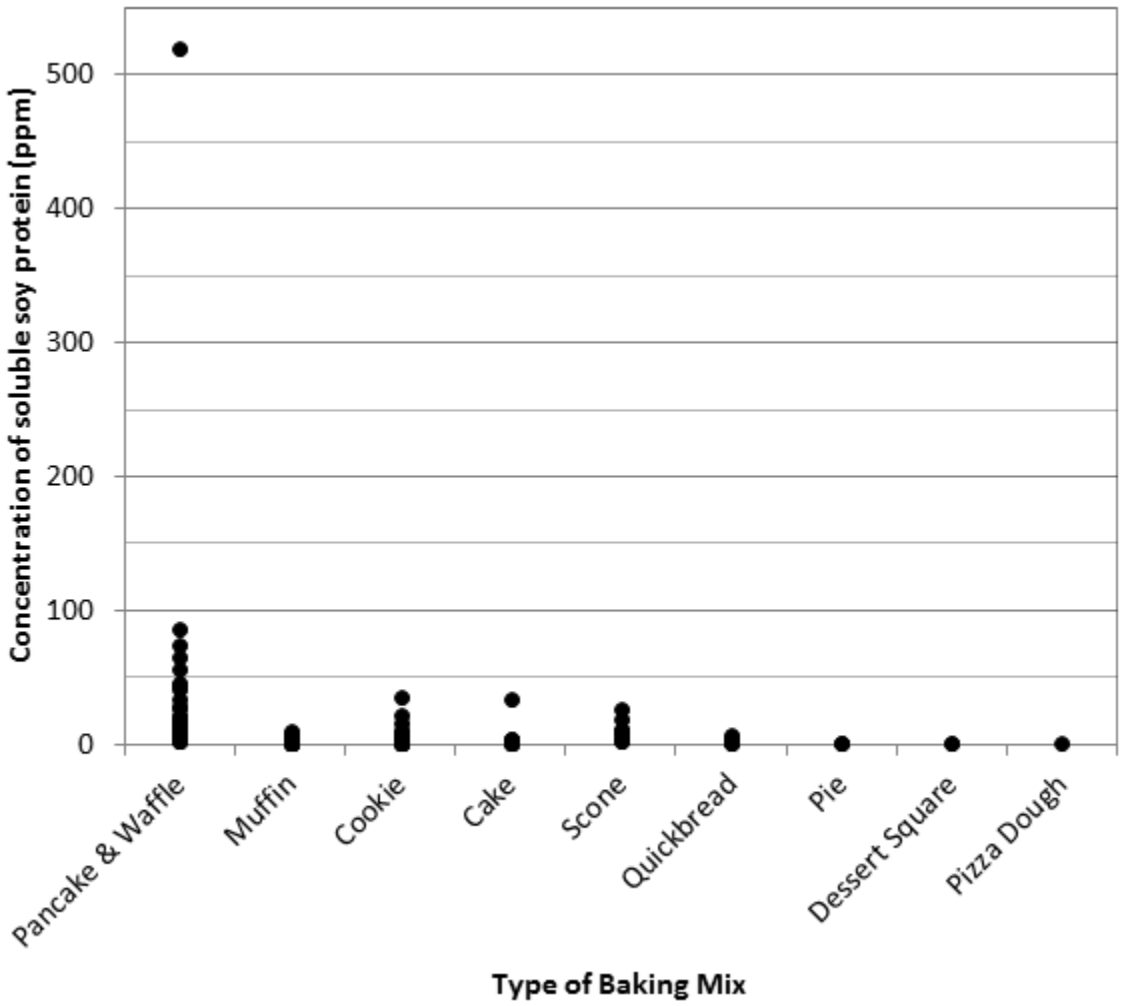


Note: Only values above the limit of detection are displayed in the graph

Figure 4. Concentration of soluble soy protein detected in multiple ingredient finished foods by product type (excluding baking mixes; arranged by decreasing number of positive samples)

The very low levels of soy detected in samples of baked goods, breads, cookies, and crackers/crispbreads/croutons generally support that soy was adventitiously present. Relative to these product types, the greater percentage of baking mix samples (which were generally wheat flour-based) found positive for slightly higher levels of undeclared soy may indicate that this type of product might be more prone to cross-contamination during manufacturing (likely in addition to adventitious presence of soy). However, it should be emphasized that these dry baking mixes were analyzed as sold and not prepared as they would be consumed. The single pancake/waffle mix product that had a relatively elevated level of soy must be prepared prior to consumption. Taking into account the directions for preparation on the mix, the concentration of soy in the product

as consumed would be lower and closer to the levels of soy noted in some of the ready-to-eat foods sampled in this survey. The levels detected in multiple ingredient grain-based finished food samples do not suggest that soy was intentionally added.



Note: Only values above the limit of detection are displayed in the graph

Figure 5. Concentration of soluble soy protein detected in multiple ingredient finished foods by product type (baking mixes only; arranged by decreasing number of positive samples)

4 Conclusions

This targeted survey obtained baseline information regarding the presence and levels of undeclared soy in single and multiple ingredient prepackaged grain-based foods.

Very low levels of soy were detected in flour samples (particularly in wheat flours), which supports that soy was adventitiously present. Similarly low levels of soy were also detected in samples of baked goods, breads, cookies, and crackers/crispbreads/croutons.

Relative to the rest of the product types sampled in this survey, a greater percentage of baking mixes (which were generally wheat flour-based) were found positive for slightly higher levels of undeclared soy. This may indicate that baking mixes might be more prone to cross-contamination during manufacturing (likely in addition to adventitious presence of soy). However, it should be emphasized that these dry baking mixes were analyzed as sold and not prepared as they would be consumed.

The levels of soy detected in both single and multiple ingredient grain-based finished food samples in this survey do not suggest that soy was intentionally added.

Since not all detectable levels of soy pose a risk to consumers, positive results were first considered by the CFIA for their potential risk. Appropriate follow-up actions were initiated that reflected the magnitude of the human health concern. Actions may include further analysis, notification to the producer or importer, follow-up inspection, additional directed sampling, a food safety investigation (which may involve a health risk assessment conducted by Health Canada), and recall of products.

5 Appendix

Summary of Samples Found Positive for Undeclared Soy by Product Type

Product Type and Origin	Number of Positive Samples	Minimum Level of Soluble Soy Protein Detected (ppm)	Maximum Level of Soluble Soy Protein Detected (ppm)	Product Type and Origin	Number of Positive Samples	Minimum Level of Soluble Soy Protein Detected (ppm)	Maximum Level of Soluble Soy Protein Detected (ppm)
Barley Flour				**Cookie Baking Mix**			
Domestic	1	-	6.8	*Domestic*	1	-	7.6
*Unspecified**	1	-	2.8	*Unspecified**	29	0.5	36
Oat Flour				**Dessert Square Baking Mix**			
Domestic	2	0.6	0.9	*Unspecified**	2	1.1	1.4
Wheat Flour				**Muffin Baking Mix**			
Domestic	11	0.8	30	*Domestic*	15	0.5	7.6
Imported	2	0.9	19	*Imported*	1	-	3.8
*Unspecified**	1	-	1.2	*Unspecified**	16	0.8	11
Rye Flour				**Pancake & Waffle Baking Mix**			
Domestic	5	0.8	7.6	*Domestic*	3	3.8	11
*Unspecified**	1	-	1.2	*Imported*	12	28	520
Bread				*Unspecified**	22	3.0	22
Domestic	2	0.5	0.9	**Pie Baking Mix**			
*Unspecified**	1	-	10	*Unspecified**	3	1.2	1.5
Baked Goods				**Pizza Dough Baking Mix**			
Domestic	2	1.2	1.3	*Unspecified**	1	-	0.9
Cookies				**Quickbread Baking Mix**			
*Unspecified**	1	-	1.0	*Unspecified**	7	0.6	7.6
Crackers				**Scone Baking Mix**			
*Unspecified**	1	-	2.4	*Unspecified**	10	2.0	26
Cake Baking Mix							
Imported	8	0.6	4.0				
*Unspecified**	10	0.6	34	**Overall**	**171**	**0.5**	**520**

*Unspecified refers to those samples for which the country of origin could not be determined from the product label

6 References

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